MAR 1 1 2013

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ABAXIS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K130113

1. Applicant Information:

Date Prepared:	March 4, 2013
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Dennis M. Bleile, PhD
Phone Number:	(510) 675-6515
Fax Number:	(510) 405-8871

2. Device Information:

Classification:	Class I- Reserved (point-of-care)
Trade Name:	Piccolo® Lactate Test System
Classification Name:	Lactate Test system 862.1450

3. Identification of legally marketed device to which the submitter claims equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
i-STAT Lactate/LAC	Originally, i-STAT Corporation (Princeton, NJ) Currently, Abbott Point of Care Inc. (Abbott Park, IL)	K982071	06/29/98

Summary of Safety and Effectiveness (continued)

4. Description of the Device:

The Piccolo MetLac 12 Panel Reagent Disc (which contains the Piccolo Lactate Test System) is designed for lithium heparinized whole blood and lithium heparinized plasma. The disc meters the required quantity of sample and diluent, mixes the sample with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted sample mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer.

5. Statement of Intended Use:

The Piccolo® Lactate Test System (presently contained on the MetLac 12 Panel Reagent Disc) used with the Piccolo xpress™ Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of lactate concentration in heparinized whole blood or heparinized plasma in a clinical laboratory setting or point-of-care location.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

Table 1 Outlines the technological characteristics of the Piccolo Lactate Test System in comparison to the legally marketed predicate device.

Summary of Safety and Effectiveness (continued)

Table 1:
Specification Comparison: Piccolo Lactate Test System & Predicate Device

	Piccolo xpress Chemistry Analyzer	Abbott i-STAT System K982017
Intended Use	Quantitative analysis of lactic acid	Quantitative analysis of lactic acid
Methodology	Enzymatic colorimetric assay	Enzymatic amperometric assay
Sample Type	Heparinized venous whole blood and heparinized plasma	Arterial, venous, or capillary whole blood (with or without heparin)
Dynamic Range	0.30 – 9.99 mmol/L	0.30 – 20.00 mmol/L
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer Active ingredients: Lactate Oxidase (LOX) Peroxidase (Horseradish) 4-aminoantipyrine (4-AAP) 3,5-dichloro-2-hydroxy-benzenesulfonic acid (DHBSA)	Immobilized enzyme on a biosensor and liquid reagents Active ingredients: Lactate Oxidase (LOX) Lactate
Temperature of Reaction	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	i-STAT Lactate is automatically calibrated during each analysis cycle using lactate in the test cartridge
Testing Environment	Professional use	Professional use
Sample Size	Approximately 100 µL	95 µL

Summary of Safety and Effectiveness (continued)

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence.

Tables 2 & 3 summarize the results of clinical and non-clinical tests performed using the Piccolo Lactate Test System.

Linearity:

Table 2:
Summary of Linearity

	Lactate
Slope	1.00
Intercept	0.00
Corr. Coefficient	0.999

Sensitivity – Limits of Blank (LOB), Limits of Detection (LOD), and Limits of Quantitation (LOQ):

A sensitivity study was conducted according to CLSI EP17-A. Seven pools, including the lowest non-zero lactate calibrator (normal human plasma pool 1.78 mmol/L), five dilutions of the lowest calibrator in saline, and a saline blank were assayed.

Each pool was assayed sixty times, three times on each of 20 Piccolo xpress Chemistry Analyzers on one day. The pools were analyzed using the Piccolo lactate rate at each level and a linear regression calibration line was calculated with the slope and intercept serving as the calibration factors. The lactate concentrations were then calculated from the calibration factors.

The LOB, LOD, and LOQ were determined for the Abaxis lactate test system.

LOB – The values for the blank were found not to be Gaussian. Therefore, the LOB was determined as the non-parametric 95th percentile. This value is 0.02 mmol/L.

LOD – The values of the low level samples were found also not to be Gaussian. Hence, LOD was determined non-parametrically. The low level samples were checked to see where 5% or fewer of the observed measurements were below the LOB. The lowest sample tested had a recovered mean value of 0.068 mmol/L and its 5 percentile limit was at 0.057 which is significantly above the LOB. Hence, the LOD is 0.07 mmol/L.

LOQ – The point at which 20% total error (= %bias + 2*%CV) was determined by linear regression analysis. Based on this determination the LOQ is 0.11 mmol/L.

Summary of Safety and Effectiveness (continued)

Precision:

Precision studies were designed to evaluate within-run and total precision of the Lactate Test System when run on the Piccolo xpress Chemistry Analyzer.

Table 3:
Summary of Within-Run and Total Precision of Lactate Assayed on the Piccolo xpress Chemistry Analyzer: Control and Plasma Pool Testing

	Within-Run	Total
	Lactate (mmol/L)	
Control Level 1 (N=80)		
Mean	1.62	1.62
SD	0.03	0.04
%CV	1.8	2.2
Control Level 2 (N=80)		
Mean	3.63	3.63
SD	0.05	0.08
%CV	1.5	2.3
Control Level 3 (N=80)		
Mean	6.99	6.99
SD	0.18	0.36
%CV	2.6	5.2
Human Plasma Pool 1 (N = 40)		
Mean	0.86	0.86
SD	0.02	0.02
%CV	1.9	1.9
Human Plasma Pool 2 (N = 40)		
Mean	6.22	6.22
SD	0.20	0.20
%CV	3.2	3.2

Summary of Safety and Effectiveness (continued)

Results for Fresh Whole Blood Precision Testing at Abaxis

Table 4
Summary of Inter-assay Precision Study on Whole Blood for Lactate Assayed on the Piccolo xpress Chemistry Analyzer

	Lactate (mmol/L)					
	Sample 1	**Sample 2**	**Sample 3***	**Sample 4**	**Sample 5**	**Sample 6***
Mean	1.02	1.48	1.37	6.21	7.77	6.61
SD	0.02	0.03	0.02	0.20	0.22	0.18
%CV	2.1	2.2	1.7	3.3	2.9	2.8
n	20	20	20	20	20	20

*Note: Samples 1, 2, 4, & 5 were tested with one disc lot; Samples 3 & 6 were tested with a 2nd disc lot.

Results for Fresh Whole Blood Precision Testing at Three External Sites

5a. Whole Blood Precision at Site 1

	WB 1 Operator 1	**WB 2 Operator 1**	**WB 3 Operator 1**	**WB 4 Operator 1**
Mean	1.52	4.67	0.72	4.13
SD	0.03	0.17	0.02	0.12
%CV	2.1%	3.7%	2.2%	3.0%
Count	10	10	10	10
	WB 1 Operator 2	**WB 2 Operator 2**	**WB 3 Operator 2**	**WB 4 Operator 2**
Mean	1.50	4.59	0.70	4.17
SD	0.02	0.10	0.02	0.17
%CV	1.7%	2.3%	2.5%	4.1%
Count	10	10	10	10
	WB 1 Combined	**WB2 Combined**	**WB 3 Combined**	**WB 4 Combined**
Mean	1.51	4.63	0.71	4.15
SD	0.03	0.15	0.02	0.15
%CV	2.0%	3.1%	2.7%	3.5%
Count	20	20	20	20

Summary of Safety and Effectiveness (continued)

5b. Whole Blood Precision at Site 2

	WB 25 Operator 1	WB 26 Operator 1	WB 27 Operator 1	WB 28 Operator 1
Mean	1.00	6.18	1.09	5.88
SD	0.03	0.21	0.03	0.32
%CV	2.8%	3.4%	2.6%	5.5%
Count	10	10	10	10
	WB 25 Operator 2	**WB 26 Operator 2**	**WB 27 Operator 2**	**WB 28 Operator 2**
Mean	1.02	6.38	1.12	5.90
SD	0.02	0.25	0.03	0.17
%CV	1.7%	3.9%	2.3%	2.9%
Count	10	10	10	10
	WB 25 Combined	**WB 26 Combined**	**WB 27 Combined**	**WB 28 Combined**
Mean	1.01	6.28	1.10	5.89
SD	0.03	0.24	0.03	0.25
%CV	2.5%	3.9%	2.7%	4.2%
Count	20	20	20	20

Summary of Safety and Effectiveness (continued)

5c. Whole Blood Precision at Site 3

	WB 101 Operator 1	WB 102 Operator 1	WB 103 Operator 1	WB 104 Operator 1
Mean	0.88	5.93	1.09	7.76
SD	0.03	0.24	0.03	0.28
%CV	3.3%	4.1%	3.0%	3.7%
Count	10	10	10	10
	WB 101 Operator 2	**WB 102 Operator 2**	**WB 103 Operator 2**	**WB 104 Operator 2**
Mean	0.88	5.86	1.06	7.76
SD	0.04	0.14	0.03	0.28
%CV	4.3%	2.5%	2.9%	3.5%
Count	10	10	10	10
	WB 101 Combined	**WB 102 Combined**	**WB 103 Combined**	**WB 104 Combined**
Mean	0.88	5.89	1.08	7.76
SD	0.03	0.20	0.03	0.27
%CV	3.8%	3.3%	3.2%	3.5%
Count	20	20	20	20

Method Comparison with Predicate Device:

The method comparison study was conducted at an external site to assess the accuracy of the Abaxis lactate method. Results obtained from the Piccolo xpress Chemistry Analyzer were compared with results obtained from the predicate device, i-STAT lactate test (Abbott), when testing aliquots of the same samples tested side-by-side in singlicate.

Heparinized whole blood from 126 subjects was tested on the Piccolo xpress Chemistry Analyzer and the predicate device. A good distribution of lactate values was obtained. Each sample was run on one (1) of four (4) Piccolo xpress Chemistry Analyzers and on one (1) i-STAT analyzer.

Standard linear regression analysis was used for estimation of the slope, intercept, and correlation coefficient. Deming regression analysis was also performed. The results of these studies are shown in Table 6 below.

Summary of Safety and Effectiveness (continued)

Table 6:
Method Comparison Data for Lactate Assayed on the Piccolo xpress Chemistry Analyzer and the i-STAT Lactate System

Parameters	Statistics
Piccolo Lactate Test System: singlicate values	126
i-STAT Lactate: singlicate values	126
Piccolo Lactate Test System Mean	2.92 mmol/L
i-STAT Lactate Mean	2.78 mmol/L
Piccolo Lactate Test System Std. Dev.	2.04 mmol/L
i-STAT Lactate Std. Dev.	1.99 mmol/L
Piccolo Lactate Test System range of samples	0.30 – 9.88 mmol/L
i-STAT Lactate range of samples	0.42 – 9.85 mmol/L

	Linear Regression	Deming Regression
N	126	126
Slope (95% CI)	1.02 (1.01 to 1.04)	1.03 (0.99 to 1.06)
Intercept (95% CI)	0.13 (0.07 to 0.19)	0.06 (-0.01 to 0.14)
Correlation Coefficient, R	0.996	0.996
R^2	0.992	0.992
Sy|x (Std. Error of Estimate)	0.19	0.19

The data indicate good agreement between the values obtained by the Piccolo xpress Chemistry Analyzer and the i-STAT System for lactate.

Sample Type Comparison:

A study was conducted to examine and compare results for heparinized whole blood and heparinized plasma on the Piccolo® xpress Chemistry Analyzer.

Heparinized whole blood and heparinized plasma comparability was established for lactate.

Interference Studies – Endogenous Substances:

The interference studies for physiological substances used supplemented human serum pools to assess the effects of potential interferents on the Piccolo Lactate Test System. Plasma pools for the physical interference study were prepared according to CLSI EP7-A2. The test pools contained different levels of the potential interferent

Summary of Safety and Effectiveness (continued)

under investigation. At least four (4) test pools and a control pool were prepared for each. Two levels of lactate were used in all testing.

Further, each interferent was tested at increasing levels of interfering substances. Hemoglobin interference was measured using human red blood cell hemolysate, icterus interference used a concentrate of conjugate and unconjugated bilirubin, and lipemic interference used Intralipid. Acceptance limits of ± 10% of the base line (0 interferent) were used for both levels of lactate to determine the limits. In this way the limits were determined to be: hemolysis 500 mg/dL, icterus 15 mg/dL, and lipemia 3,000 mg/dL.

Interference Studies – Exogenous Substances:

Forty-one drugs and other substances were selected as potential interferents with the lactate method based on recommendations by Young DS. Effects of drugs on clinical laboratory tests, 3rd ed. Washington, DC: AACC Press, 1990, and CLSI EP7-A2. Human plasma pools were prepared that contained lactate at 0.70 and 2.60 mmol/L.

Only two (2) substances at the concentrations listed below significantly interfered with lactate recovery. These are dopamine and L-dopa. After titration, these were found not to interfere at 0.52 (dopamine) and 0.5 (L-dopa) mg/dL.

Table 7

Exogenous Substances that Interfered with the Lactate Test

Substance	Concentration	% Interference[A]
Dopamine	13	85% dec
	0.52	<10% dec
L-dopa	5	49% dec
	0.5	<10% dec

[A] dec = decrease

Reference Interval Determination:

The reference interval for the Piccolo Lactate Test System was determined in accordance with CLSI C28-A3C by testing 130 heparinized whole blood samples from apparently healthy (self-reported) individuals. The interval was defined by the limits of the central 95% of values tested and was determined to be 0.53 – 2.10 mmol/L.

8. Conclusions

The clinical and non-clinical tests performed for lactate, when run on the Piccolo xpress Chemistry Analyzer, demonstrate that the test system is as safe, effective and performs as well as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 11, 2013

Abaxis, Inc.
c/o Dennis Bleile, PhD
3240 Whipple Rd.
Union City, CA 94587

Re: k130113
Trade/Device Name: Piccolo® Lactate Test System
Regulation Number: 21 CFR § 862.1450
Regulation Name: Lactic acid test system
Regulatory Class: I, meets limitations of exemptions per 21 CFR § 862.9 (c)(9)
Product Code: KHP
Dated: January 14, 2013
Received: January 22, 2013

Dear Dr. Bleile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130113

Device Name: Piccolo® Lactate Test System

Intended Use:

The Piccolo® Lactate Test System (presently contained on the MetLac 12 Panel Reagent Disc) used with the Piccolo xpress™ Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of lactate concentration in heparinized whole blood or heparinized plasma in a clinical laboratory setting or point-of-care location.

Indications for Use:

Lactate measurements are used in the diagnosis and treatment of lactate acidosis, monitoring tissue hypoxia, and diagnosis of hyperlactatemia.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130113